Research Agreement and Research and Ethics Review Committee (RERC) Policy #AD 07-12-004

Purpose

The purpose of this policy is to outline the procedures for the review and approval of applications submitted to the Iowa Department of Public Health (IDPH) for access to department data for use in a research project as allowed by statute or Administrative Code.

Definitions

Confidential Public Health Information, Record or Data: A record, certificate, report, data, dataset, or information which is confidential under federal or state law. As a general rule, public health records which contain personally identifiable information of a health-related nature are confidential under Iowa Law. More information about confidential public health records can be found in **IDPH Policy #ES 01-16-002, Disclosure of Confidential Public Health Information, Records, or Data.**

Data Custodian: The IDPH employee who is in the position responsible for the safe custody, transport, and storage of the data. The data custodian is responsible for the technical environment and database structure that hosts data. The custodian for IDPH data may be indicated by statute (e.g., State Registrar of Vital Records); however, the physical custodian for the majority of IDPH data is the Bureau of Information Management and Bureau of Health Statistics.

Data Owner: The IDPH employee who is in the position that is responsible for the dataset, as designated by the director or director's designee or as indicated by statute. The data owner may authorize or deny access to certain data within IDPH, and is responsible for accuracy and integrity of the data and timely response to data inquiries. However, the decision for release of data for the purpose of research is finalized by the Research and Ethics Review Committee.

Data Sharing Agreement (DSA): A legal contract between IDPH and any external entity (including other departments within state government and Regent's institutions), or between two internal IDPH programs in which parties agree to the exchange of specified variables within an IDPH dataset, or in some cases paper files, at identified intervals of time, and use of the data does not meet the definition of research constituting a need for a Research Agreement. More information about DSAs can be found in **IDPH Policy #AD 01-16-001 Data Sharing Agreement (DSA) Policy.**

Data Steward: The IDPH employee who is in the position responsible for data content, context, and associated rules for interpretation of each data source. The data steward(s) serves as an intermediary between the data owner and data custodian. Data stewards have the responsibility of ensuring that the appropriate steps are taken to protect the data and that respective policies and guidelines are being properly implemented. The data owner and steward might be the same person.

Implied Confidential Public Health Data: Data which can be used to indirectly establish the identity of a person named in a confidential public health record by the linking of the released information or data with external information which allows for the identification of such person. More information about implied confidential public health data can be found in **IDPH Policy #ES 01-16-002, Disclosure of Confidential Public Health Information, Records, or Data.**

Institutional Review Board (IRB): Also known as an independent ethics committee or ethical review board is a committee that has been formally designated to approve, monitor, and review

biomedical and behavioral research involving humans. IDPH does not have an internal IRB; therefore, an external IRB approval may be sought by the researcher depending on the project partners.

Personal Gain: Efforts by any employee that benefit an IDPH employee personally or professionally and where the "effort" is outside of the scope of normal job duties. Examples of efforts qualifying as "personal gain" include, but are not limited to: using IDPH data for a dissertation or other graduate work, using IDPH data in consulting work, or in other supplemental employment.

Primary Investigator (PI): The individual conducting the research. The PI is responsible for the management of the research agreement. The PI is the point of contact for all communication with IDPH related to the review of the application and is also responsible for non-IDPH individuals who are authorized to access data received through the research agreement.

Research: A systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for personal gain. Examples of "research" are included in **Appendix A**.

Research Agreement: A contract between IDPH and any external entity (including other departments within state government and Regent's institutions) in which IDPH agrees to release specific variables within a dataset that includes parameters of time and geography as requested in a research application. A research agreement is required when the receiving entity intends to use the requested dataset for the purpose of research and is bound by the confidentiality requirements in the research agreement.

Research and Ethics Review Committee (RERC): The Research and Ethics Review Committee (RERC) is responsible for evaluating and approving or denying requests for IDPH-owned data for the purposes of research. The committee composition, roles and responsibilities are outlined in this policy.

Policy

All applications for access to confidential or implied confidential IDPH data requested for the purpose of research must be reviewed and approved by the Research and Ethics Review Committee (RERC). The RERC is also responsible for assuring documentation is sufficient to meet the requirements for committee review.

The duties of the RERC do not include review or approval of data sharing agreements where research is not the basis for the request. Non-research requests for confidential or implied confidential data must be processed according to the procedure outlined in IDPH Policy #AD 01-16-001 Data Sharing Agreement (DSA).

The duties of the RERC do not include review or approval of Open Records requests for public data. Open Records requests must be processed according to the procedures outlined in IDPH Policy #IM 11-04-015, Open Records.

Procedures

Employee

If an employee receives a request for confidential or implied confidential IDPH data from someone **outside** of IDPH, the employee should assess whether the requestor will be using the data for the purpose of research.

- **If the employee believes the request is research-related**, then the requester should be referred to the RERC Coordinator at rerc@idph.iowa.gov.

- **If the employee is not sure whether the request is research-related**, then the requester should also be referred to the RERC Coordinator at rerc@idph.iowa.gov.
- **If the request is unrelated to research**, then the request should be referred to IDPH's Data Management Program.

Employee Requests for Access to Data for Research
IDPH employees requesting access to confidential or implied confidential IDPH data for research must submit an application to the RERC.

The employee is exempt from this process if data requested are part of an IDPH employee's scope of work or is required to complete IDPH assigned duties.

Research and Ethics Review Committee (RERC)

Duties of the RERC
The RERC is responsible for receiving and processing all applications for research agreements and research-related requests for IDPH data. This includes applications from IDPH staff and non-IDPH staff. The following sections detail the procedure for processing research agreement applications and research-related requests.

All applications will be placed in queue for RERC review upon receipt of necessary documentation from the PI. After receipt of the complete application, the documents will be reviewed and a response provided to the PI typically within one month, but no more than three. The timing of reviews and final decisions is dependent on completeness of the application, PI responsiveness to comments or questions from the RERC, and the number of applications under review at that time.

Composition of the RERC
The committee will have three permanent members designated by the IDPH Executive Team:

A. Bureau Chief for the Bureau of Health Statistics (Vital Records)
B. IDPH Medical Director/State Epidemiologist (Deputy State Epidemiologist may serve in the absence of the Medical Director)
C. Data Management Program Manager or other comparable individual in a position with duties that include IDPH data management.

The committee may have additional members meeting the following criteria:

- Must have work experience and/or academic training in health statistics, research methodology or epidemiology of acute or chronic disease.
- A temporary subject matter expert (e.g., data owner, steward, custodian or in some cases a bureau chief or other administrator).

Quorum criteria

- Decisions are made by consensus, when at least two permanent members must agree.

Criteria for IDPH Employee Use of Research Agreements when the IDPH Employee is the PI

There are situations when IDPH employees must submit an application to the RERC for the use of IDPH data. Explanations are listed below:

1) An IDPH employee <u>MUST</u> submit an application for access to IDPH data to the RERC if:

a. Data requested are being used for a research project outside of the scope of the employee's work or is not required to complete IDPH assigned duties,

OR

b. Data requested are being shared with an outside person or entity for use in a research project,

OR

c. Data requested will be used to draft a manuscript for publication in a peer-reviewed journal, unless data release follows IDPH's data release guidelines.

OR

d. Data requested will be used outside the normal scope of job duties and for personal gain of any kind.

The RERC and the Data Management Program are available to IDPH employees for consultation on release concerns and guidance as to the need of an application.

Any data release to an external entity that has not been approved via this process must follow IDPH's *Policy for the Disclosure of Confidential Public Health Records* #ES 06-13-002 and IDPH's *Data Sharing Agreement (DSA) Policy* #01-16-001.

Application Requirements for IDPH Research Agreements- *New and Continuing*

All application and guidance materials for IDPH Research Agreements are located at: http://idph.iowa.gov/PublicHealthData/research-requests).

All NEW applications submitted to the RERC for consideration must include the following documents:

- Application for research agreement
- List of requested variables or files
- Copy of IRB application (all documentation required) and approval or exemption*
- Resume or biosketch for PI

*Conditional project approval may be granted when IRB approval is pending; however, no data will be released until IRB approval is obtained and submitted to IDPH.

All applications submitted to the RERC for consideration for CONTINUATION must include the following documents:

- Current Research Agreement #, date current Agreement was effective, and a description of any changes in the research project
- Updated application for research agreement
- List of requested variables or files
- Copy of updated IRB application (all documentation required) and approval or exemption*

*Conditional project approval may be granted when IRB approval is pending; however, no data will be released until IRB approval is obtained and submitted to IDPH.

After approval of a **NEW** or **CONTINUATION** application, the PI will be asked to complete the following:

- Research agreement between IDPH and PI, including additional signature page for other persons involved in the project

Based on the necessary documentation provided, the RERC will assess whether proposals meet the following requirements:

- IDPH possesses the legal authority to release or withhold the data requested.
- Knowledge gained from this research agreement must contribute to the understanding of health conditions or to an issue related to public health and be of intrinsic value to the people of Iowa. Must be bona fide research and not conducted for personal gain[1].
- Data requested must be used **for research purposes only**. The data may not be transferred or reused by the Primary Investigator (PI) without seeking explicit and additional approval of the RERC. IDPH data may never be given or sold by a PI or other person(s) or entities, unless authorized by the original agreement.
- Research must include ethical and legal considerations within the study design.
- Research must include realistic outcomes or goals.
- PI must verify the means to compensate IDPH for any charges resulting from the fulfillment of the research agreement (i.e., data retrieval fees).
- PI must adhere to contract data security standards outlined in the research agreement.
- PI must provide drafts of any public presentation (e.g., manuscripts, or presentations) containing IDPH data for pre-approval by the Data Management Program Manager. PI is responsible for oversight of any public presentation of IDPH data. IDPH data may be presented without RERC authorization within the data release guidelines outlined in the research agreement. Questions surrounding pre-approval of data presentation may be submitted to the RERC at any time.
- PI must agree to submit a continuation request, if needed.
- PI must confirm destruction of data, which may include confirming data destruction by an uninvolved or impartial third party.

The RERC reserves the right to request documentation outside of the parameters listed in the policy.

Consultation with the RERC prior to submission of application may be appropriate under certain circumstances. The RERC is available for consultation on release concerns and guidance when an application is needed or not necessary.

Expiration of Research Agreement

The term of the Research Agreement is two years from the starting effective date, unless terminated early in accordance with the Research Agreement. If the PI anticipates their project continuing past the expiration date, they must resubmit an application for continuation of the agreement at least 60 days prior to the expiration date of the agreement so that there is no lapse.

If the PI does not submit an application for continuation of the Research Agreement they must destroy the data in a way that renders the data unidentifiable and useless. In addition, the *Confirmation of Destruction* form must be completed and returned to the RERC upon completion of the project. This must be done within 60 days of the expiration date of the agreement or completion of the project, whichever occurs soonest, unless an application for continuation has been submitted.

[1] 641.175.10(2)(b)

Oversight for the RERC

Oversight of the function and composition of the RERC is the responsibility of Executive Team.

Division/Bureau Responsibilities

The Bureau of Planning Services is responsible for the coordination of the RERC and all applications received.

Responsibility for fulfilling the data requests approved by the RERC is that of the data owner and custodian. The data owner and data custodian will receive approval in the form of a copy of the research agreement from the RERC. If there is not a data owner or custodian identified for a dataset, the RERC will identify the appropriate contact to fulfill the request. Requests for data will be managed by the Data Management Program in the Bureau of Planning Services.

Policy/Procedure Violations

For IDPH employees- violations of the policy are grounds for disciplinary action, up to and including discharge.

For all persons and entities participating in a research agreement with IDPH – IDPH has the authority to employ penalties for misuse of data. Penalties for violations of the research agreement may include, but are not limited to:

- Revocation of the research agreement
- Notice to the sponsoring IRB
- Notice to the immediate supervisor of the violating party
- Notice to the IDPH Director
- Immediate revocation of data access
- Restitution of funds to the grantor agency as appropriate
- Removal of the violating party from the particular project, or special monitoring of future work
- Letter of reprimand, probation, suspension, salary reduction, rank reduction or termination of employment for the violating party
- Withdrawal or correction of all pending or published documents emanating from the research where the misconduct was found
- Future research activities involving IDPH data may be denied
- Other sanctions as authorized by federal or state law

The PI is responsible for all violations of the research agreement for all co-signatories of the agreement.

Appendix A- Policy #AD 07-12-004

Examples of Research and Non-Research Requests

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, MUST be reviewed by the RERC.

Example A

A researcher is requesting access to five years' worth of birth certificate data. The data requested does not contain patient-identifying information, but will be used as part of a research project.

Explanation A

Data are being used for a research project. It does not matter whether the data will contain identifying information. All requests for data used in a research project must be routed through the process for approval through the RERC.

Example B

A staff person at IDPH is pursuing a doctoral degree. As part of her dissertation, the staff person needs access to data from the Trauma Registry. This person has access to Trauma Registry data due to her normal job duties, but needs to extract a dataset from the registry for use on her dissertation project. The dissertation project is not part of her normal job duties and is worked on outside of IDPH hours and on a personal computer.

Explanation B

Even though this staff person had access to the data, the dissertation project is outside of her normal scope of duties. That is reason alone to warrant RERC review. In addition, she intends on analyzing data on a computer outside IDPH. This person must submit an application to the RERC.

Example C

The Iowa Department of Human Services (DHS) is conducting a study to determine the percentage of low-income Iowa residents who are eligible for Medicaid that enroll in Medicaid either through IDPH or DHS. DHS is requesting the list of Iowa residents enrolled in Medicaid-sponsored maternal and child health programs, including patient names. DHS plans to publish the results of this study in a professional health journal with the intent to increase physician awareness of Medicaid enrollment statistics.

Explanation C

Even though the requestor of data in this example is another state agency, the agency is using the data for a research project. Anytime IDPH data might be used for research or publication, the request for data must go through the RERC.

Example D

A staff person at IDPH works routinely on situations involving infectious disease. This person began working with a statistician at a local university to determine if there were demographic patterns linked to the incidence of infectious disease. The statistician needed access to IDPH infectious disease data that had potentially-identifying information. The outcomes of the analysis for the project were submitted to a health journal for publication.

Explanation D
The work of this project is within the scope of the IDPH employee's normal job duties; however, the data is being shared with someone external to IDPH and for the purpose of research. This project and permission to share data with the statistician should be requested through the RERC.

Example E
A University of Iowa graduate student is working on a project in which they need access to data from the Iowa Registry of Congenital and Inherited Disorders.
Explanation E
Although the registry is maintained at the University of Iowa, it is still owned by IDPH. The student would need to submit an application to the RERC as well as receive a letter of agreement from the director of the registry.

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, Do NOT need to be reviewed by the RERC.
Example F
The National Marrow Donor Registry has requested that IDPH match the list of eligible Iowa donors to Iowa residents who have died in the past year. The Donor Registry is making this request so that the Registry has a current list of donors.
Explanation F
This request does not involve use of the data for research; however, a data sharing agreement must be in place before data may be shared.

Example G
The Iowa Department of Human Services (DHS) is evaluating the percentage of low-income Iowa residents who are eligible for Medicaid that enroll in Medicaid either through IDPH or DHS. DHS is requesting the list of Iowa residents enrolled in Medicaid-sponsored maternal and child health programs, including patient names. The results of the evaluation are being used to assess DHS programs and will not be released outside of their department.
Explanation G
Other state agencies may request data from IDPH for use internally. A data sharing agreement is sufficient as long as the data is not released outside of the agency and is not used as part of a research project.

Example H
A statistician at a local university agreed to contract with IDPH as a consultant for non-research purposes. As part of the contract, the statistician needed access to large files of outpatient data with patient names and other identifiers.
Explanation H
A data sharing agreement should be part of the contract with the statistician, but since the work is contracted and not part of a research project, review by the RERC is not necessary.